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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,820	02/10/2006	Jae-Hong Kim	012679-114	3987
21839	7590	06/09/2008	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404				MCCORMICK, MELENIE LEE
ART UNIT		PAPER NUMBER		
1655				
NOTIFICATION DATE			DELIVERY MODE	
06/09/2008			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/551,820	KIM, JAE-HONG	
	<b>Examiner</b>	<b>Art Unit</b>	
	MELENIE MCCORMICK	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 March 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3 and 17-19 is/are pending in the application.  
 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1, 3, 17-19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 02/07/08.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Applicants remarks with claim amendments submitted 6 March 2008 have been received and considered.

Claims 2 and 4-16 are cancelled.

Claims 18-21 have been added.

Claims 1, 3, and 17-21 are pending.

New Claims 20-21 are withdrawn from consideration as being drawn to a non-elected invention. These claims are drawn to the invention described as Group III in the restriction requirement mailed 24 May 2007 and are considered independent and distinct from the elected invention for the reasons set forth in the Requirement for Restriction mailed 24 May 2007.

Claims 1, 3, and 17-19 are presented for examination on the merits.

### ***Requirement for Information***

Applicants have replied to the Requirement for Information set forth in the previous Office Action. Applicant's reply states that upon information and belief, the information requested (the amount of pelargonidin which is present in black rice which was extracted by the methods instantly disclosed) is unknown and/or is not readily available to Applicant. Applicant's response which states that the amount is unknown and/or not available is sufficient to fulfill the Examiner's request for information presented in the previous Office action.

***Withdrawn Rejections***

The previous Claim objections have been withdrawn in view of the claim amendments, which remove the brackets from the term 'Formula 1' in claim 3 and amend the last phrase of the claim. The objection to claim 8 is moot since the claim has been cancelled.

The previous rejection of the claims under 35 U.S.C. 112, first paragraph has been withdrawn in view of the amendments to the claims which are now drawn to a method for treating asthma by inhibiting the accumulation of eosinophiles in cells, tissues or a body.

The previous rejection under 35 U.S.C. 112, second paragraph is moot since claim 8 is now cancelled.

The previous rejection under 35 U.S.C. 102 (b) has been withdrawn in view of the amendments to claims 1 and 17, which are now drawn to a method for treating bronchial asthma.

***Maintained Rejections***

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 stands rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nair et al. (WO 01/15553 A1) for the reasons set forth in the previous Office Action and for the reasons discussed below.

Nair et al. teach a method of treating an inflammatory response in an animal by administering to the animal a composition (fruit extract) which has anti-inflammatory activity (see e.g. claim 19). Nair et al. further teach that the inflammatory response may be asthma (see e.g. claim 20). Nair et al. also teach that the composition comprises pelargonidin (see e.g. claim 21). Because Nair et al. disclose that the anti-inflammatory activity of the extract is mediated by pelargonidin (see e.g. page 3, lines 1-14), the pelargonidin present in the extract composition (even if only a small amount), is present in an effective amount. Even if the pelargonidin were not supplied in an 'effective' amount, based on the disclosure of Nair et al. that pelargonidin has anti-inflammatory

activity (which is useful for treating an asthma), one of ordinary skill in the art would reasonably expect that adjusting the amount of pelargonidin administered to an individual in need of treatment would result in an effective treatment for asthma. Therefore one of ordinary skill in the art would be motivated to provide pelargonidin in an amount effective to treat asthma. Although bronchial asthma is not explicitly taught, a person of ordinary skill in the art would reasonably understand that bronchial asthma is commonly referred to as asthma.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7-8 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (1999) and Assem (1973) for the reasons set forth in the previous Office Action and for the reasons set forth below. Newly added claims 18-19 are also rejected under 35 U.S.C. 103 (a) for the reasons discussed below.

Kim et al. beneficially teach that black rice has been used in Korea for management of various allergic diseases (see e.g. page 31- Introduction). Kim et al. further teach that an extract of black rice was administered to rats which had been

induced with an anaphylactic response. Kim et al. further teach that administration of the extract reduced mortality in the anaphylactic rats (see e.g. page 33- Results). Kim et al. further teach that administration of the black rice extract also reduced histamine release in allergy- induced rats (see e.g. page 33 –Effect of OSHT on serum histamine release). Because the black rice extract is a methanol extract (see e.g. page 32 – Preparation of OSHT) and Applicant’s extract is an ethanol extract, it would be expected that the extract disclosed by Kim et al. would also contain pelargonidin therein. Kim et al. do not explicitly teach a method of treating bronchial asthma by administering an effective amount of a black rice extract to an individual in need thereof.

Assem beneficially teaches that bronchial asthma may be treated by administering antihistamines or inhibitors of anaphylactic mechanisms (see e.g. page 1191).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a black rice extract (which would necessarily contain pelargonidin therein) to an individual in need of treatment of bronchial asthma. One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the beneficial teaching of Kim et al. that a black rice extract was effective in reducing an anaphylactic response and in reducing histamine release. Because Assem teaches that bronchial asthma can be treated using antihistamines or inhibitors of anaphylaxis, one of ordinary skill would reasonably expect that administration of the

black rice extract with the anaphylaxis and histamine reducing effects taught by Kim et al. would treat bronchial asthma.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Nair et al.

Applicants argue that Nair et al. teaches a dietary food supplement that can be used to inhibit inflammation mediated by cyclooxygenase, while the claims of the present invention are directed toward a method of treating bronchial asthma by inhibiting the accumulation of eosinophils in the cells, tissues or body of an individual. Applicants also argue that Nair et al. fails to suggest that an effective amount of pelagonidin represented by Formula 1 could be used to treat bronchial asthma by inhibiting the accumulation of eosinophiles in the cells, tissues, or body of an individual. This is not found persuasive, as the active method steps taught by Nair are the same as those instantly claimed. As previously stated, Nair et al. teaches administration of pelargonidin to treat asthma (see e.g. claims 18-20). Therefore, any effect on

eosinophiles following the administration of pelagonidin would necessarily occur, even if it was not known at the time. In addition, as previously stated, Nair et al. disclose that the anti-inflammatory activity of the extract is mediated by pelargonidin (see e.g. page 3, lines 1-14 and claims 18 and 20). Therefore, the pelargonidin present in the extract composition (even if only a small amount), is present in an effective amount. Even if the pelargonidin were not supplied in an 'effective' amount, based on the disclosure of Nair et al. that pelargonidin has anti-inflammatory activity (which is useful for treating an asthma), one of ordinary skill in the art would reasonably expect that adjusting the amount of pelargonidin administered to an individual in need of treatment of would result in an effective treatment for asthma.

The rejection is therefore deemed proper and is maintained.

Kim et al. and Assem

Applicants argue that Kim et al. fails to teach using the black rice extract for treating bronchial asthma as well as fails to teach using the black rice extract to treat bronchial asthma by inhibiting the accumulation of eosinophiles in cells, tissues or a body. Applicants also argue that Assem does not teach how to treat bronchial asthma due to the accumulation of eosinophiles. This is not found persuasive, as it is the combination of Kim et al. with Assem that renders the instantly claimed invention obvious. As previously stated, Kim et al. teaches that black rice extract has an anti-anaphylactic and antihistamine response. Assem teaches that bronchial asthma may be treated by administering antihistamines or inhibitors of anaphylactic mechanisms (see

e.g. page 1191). It would have therefore been obvious to one of ordinary skill in the art to use anti-anaphylactic/ anti-histamine black rice extract taught by Kim et al. in order to treat asthma, which is disclosed by Assem as being treated by administering antihistamines or inhibitors of anaphylactic mechanisms. Although the references do not teach that the bronchial asthma is due to the accumulation of eosinophiles, the claims are not drawn to a method of treating bronchial asthma due to the accumulation of eosinophiles, but rather to a method of treating bronchial asthma by inhibiting the accumulation of eosinophiles in cells, tissues or a body, comprising administering an effective amount of black rice extract to an individual. The administration of a black rice extract to treat asthma, as instantly claimed, is rendered obvious by Kim et al. and Assem. Any effect that this administration would have on eosinophiles, although not explicitly taught, would necessarily occur upon the administration of the extract. The effect on eosinophiles is a functional effect and does not change the active method steps instantly claimed. The mechanism by which asthma is treated after administration takes place does not distinguish the instantly claimed method from the method rendered obvious by Kim et al. and Assem. A person of ordinary skill in the art would have had a reasonable expectation of success in treating bronchial asthma by administering a black rice extract based upon the teaching of Kim et al. and Assem, which are discussed above.

The rejection is therefore deemed proper and is maintained.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick  
Examiner  
Art Unit 1655

/Patricia Leith/  
Primary Examiner, Art Unit 1655